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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,735	10/14/2003	Shalini Sharma	18015-D4	4336

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,735

Applicant(s)

SHARMA, SHALINI

Examiner

Sudhaker B. Patel, D.Sc. Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/5/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' communication paper dated 2/5/04 is acknowledged. The claims in this application are the claims 1-3. After further review and consideration, this application is found not ready for allowance at this stage for the reasons stated below.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2/5/04 is being considered by the examiner. Signed copy of PTO Form 1449 is enclosed with this communication for applicants' record.
2. Applicants' request dated 10/14/03 for deletion of inventorship[under 37 CFR 1.63(d)(2) is considered and found persuasive. Accordingly, the inventor for the instant application has been corrected to Shalini Sharma only.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 4A. Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: The exact make up of a "Biologically active agent". The claim defines the term agent as a compound, whereas it is meant as a biologically active compound. Also, the claim remains silent for definite and exact meaning of " biological activity". An agent cannot be a single compound. Correction to:" A compound of the Formula III" is required.

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4. Claim 1 is also rejected under 35 U.S.C. 112 paragraph second because it recites component A as: "a 5 or 6 membered heteroaromatic ring having 1 or 2 ring heteroatoms selected from N, S, and O and the heteroaromatic ring is covalently bound to the remainder of the compound of Formula III by a ring carbon". The claim remains silent about the exact and definite position of covalent bond. The Formula III includes a bridge between components A and the phenyl ring as: "-(CH₂)¹⁻²-O-", whereas the description remains silent about the -CH₂-bridge-. Also, are substituents on to the heterocycle(s) excluded? Claim remains silent about the same. Correction(s) are required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kees (U.S.P. 4845231, also cited as Chemical Abstract DN 111:232835).

Kees teaches the compounds with CAS RN 123891-91-8 (= 1H tetrazole, 5-[[4-(cyclohexylmethoxy) phenyl] methyl]- as claimed herein. Additionally, Kees also teaches the utility as claimed herein.

The instant Formula III encompasses above compound with following meanings of the variables:

A = cycloalkyl with 6 ring carbon; n =1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al (J. Medicinal Chemistry, 33/1,240-5(1990), also cited as Chemical Abstract DN 112:35651).

8. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al (J. Medicinal Chemistry, 33/1,240-5(1990), also cited as Chemical Abstract DN 112:35651) as applied to claims above, and further in view of Sohda et al (EP 629624, also cited as Chemical Abstract DN 123:143900).

Musser teaches the compounds with a core: "Tetrazole-CH₂-phenyl-O-Alkylene-Heterocycle". See compounds with CAS RN # 107813-83-2; 120028-56-0; 123724-12-9; 123724-14-1.

Musser differs from the instant compounds by not having a monocyclic heterocycle as claimed herein.

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9. The other ref. Sohda et al (EP 629624, also cited as Chemical Abstract DN 123:143900) teaches compound with CAS RN#166254-03-1(+1H-Tetrazole, 5-[2-(2,5-dimethyl-4-oxazolyl) ethoxy] phenyl] ethyl]-. See also compound with CAS RN # 166253-98-1 which teaches only a –CH₂-bridge between tetrazole and phenyl ring, and also a monocyclic 5-membered heterocycle(= disubstituted oxazole) . Shoda also teaches the utility as claimed herein.

10. One of ordinary skill in art would have been motivated to select the claimed genus of compounds of Ref. Sohda, and modify the core either alone or in combination with prior art or fit into the core of compound(s) of Musser by fitting into the core of compound(s) to arrive at the compounds claimed herein.

11. While applicants claim their compounds to be novel, they are not non-obvious over the cited prior art(s). It cannot be ignored that prior art(s) as recited earlier and above are involving the concept of adjacent homologies consisting of –CH₂-group. There are ample cases recited with such homologies. Applicants' compounds are forming lower homologue(s) that the ref. compounds (in that the instant compounds have limited the –CH₂-bridge to 1 or 2) and such homologies are not deemed patentably distinct absent evidence of superior, unexpected results. Note Ex parte Ruddy 121 USPQ 427; Ex parte Nathan 121 USPQ 349; In Shetty 195 USPQ 753 regarding patentability of homologies. for adding or removing one or two methyl groups in/or on a carbon atom/bridge where none existed before, to extend the length of and alkyl chain. See also In re Grosse, 201 USPQ 57, 63 ("The known structural relationship

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between adjacent homologue, for example, supplies a chemical theory upon which a prima facie case of obviousness of a compound may rest”).

12. The motivation stems from the expectation of making compounds having equal or better pharmaceutical agent.

“Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compound(s)”. For example, one compound may suggest its homologue/isomer, because homology/isomer often have similar properties, and therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

13 Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

14. It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989). See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by prior art” regardless to the properties disclosed in the inventor’s application.

15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O Wilson at (571) 272 0661.

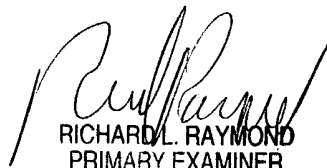
The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After

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Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sudhaker B. Patel, D.Sc. Tech.
June 17, 2004



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